DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 7, 2014

Medical Illumination International Incorporated
Mr. Robert Hess
547 Library Street
San Fernando, California 91340

Re: K140812
Trade/Device Name: MI-750 Minor Surgical Light
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FSY
Dated: July 9, 2014
Received: July 10, 2014

Dear Mr. Hess:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140812

Device Name
MI-750 Minor Surgical Light

Indications for Use *(Describe)*
The MI-750 is a fixed pattern / three level intensity procedural/minor surgical light designed to provide visible illumination of the surgical field and the patient during minor surgical and non-surgical procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.08.07 16:26:17 -04'00'

for BSA

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510 (k) SUMMARY SECTION 6

Submitter:	Medical Illumination International Inc. 547 Library St. San Fernando, CA 91340
Contact Person:	Robert Hess
Trade Name:	MI-750
Common Name:	Minor Surgical Light
Classification Number:	21 CFR 878.4580
Product Code:	FSY

Predicate Devices:

- Berchtold Chromophare E558 and E778 Light, Surgical, Ceiling Mounted
  510 (k): K083066 dated October 30, 2008
  Product Code: FSY

- Maquet Lucea LED 50 Surgical, Light System
  510(k): K113679 dated January 12, 2012
  Product Code: FSY

- Medical Illumination Int. Inc System Two (MI-1000) Light, Surgical, Fiberoptic
  510 (k): K100338 dated June 22, 2010
  Product Code FSY

Device Description:

The proposed MI-750 is a first generation fix pattern / three level intensity procedural/minor surgical light designed to provide visible illumination of the surgical field and the patient during minor surgical and non-surgical procedures.

MEDICAL ILLUMINATION INTERNATIONAL

WHERE ILLUMINATION IS DEFINED

Intended Use:

The proposed MI-750 is a fixed pattern / three level intensity procedural/minor surgical light designed to provide visible illumination of the surgical field and the patient during minor surgical and non - surgical procedures.

Description of Safety:

The performance of the MI-750 meets the general requirements for safety as defined in CEI/IEC 60601-1 and IEC 60601-2-41 for Medical Electrical Equipment.

Substantial Equivalence:

The proposed MI-750 is a fixed pattern / three level intensity procedural/minor surgical light designed to provide visible illumination of the surgical field and the patient during minor surgical procedures. The Proposed Device is identical in function, intended use, components, technology and performance to the predicate devices: Chromophare E558 and E778 Surgical Light (Berchtold) (K083066), Lucea LED 50 Surgical, Light System (Maquet) (K113679), and System Two (MI-1000) Light, Surgical System (Medical Illumination) (K100338).

The differences between the proposed and predicate devices are limited to differences in design, material, and operational. These differences do not raise any new issues of safety and efficiency

Performance Testing:

Performance testing was conducted to verify that the MI-750 meets the requirements for Medical Electrical Equipment as defined in CEI / IEC 60601-1 and IEC 60601-2-41.

Robert Hess
QA / RA Manager
Medical Illumination International, Inc.